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July 24, 2020

VIA ECF

Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this brief on behalf of the Plaintiffs to supplement Plaintiffs' arguments set forth in the July 14, 2020 agenda letter, and those presented during the July 15, 2020 hearing, with regard to Teva's proposed use of TAR/CMML as an additional layer of document review to further exclude documents from production.

There Is No Need for TAR/CMML To Be Injected

Teva set up a straw man to be knocked down with their proposed use of TAR: purported savings in time and money. In contrast, this would only inject a massive distraction into the litigation at the very point when the bulk of discovery is beginning to

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roll out. The distraction of addressing this proposal has already been significant, and cost Plaintiffs time and money in responding.

In the brief submitted by Teva prior to the July 15, 2020 conference with the Court, Teva complained of the volume of documents and asserted the need to avoid the cost and delay attendant to human review of documents for relevancy, even with the narrowed search terms that Teva agreed to (while neglecting to acknowledge that relevancy and privilege review is for the benefit of the Defendants, not the Plaintiffs). However, on questioning by the Court, it was revealed that Teva still intends to have attorneys review every document identified as responsive, obviously content to spend whatever time and effort is needed to try to establish a reason not to produce a document hit by the search terms, and found to be responsive by the CMML application. Teva only intends to dispense with the human review of documents that are coded as unlikely to be responsive, content to let those documents disappear.

This unbalanced approach will result in the non-production of relevant documents, with little in the way of tangible benefit as a tradeoff. After applying the search terms to narrow the document set, Teva wants to apply the CMML review, which is not a proven system and is not being applied as intended (See: Declaration of Plaintiffs' E-Discovery vendor Jonathan Jaffe, attached hereto as Exhibit A) to cut out many more documents. It is most telling that Teva wants to have attorneys further exclude documents that were hit by the search terms and made it through the CMML system selection process. All the while, Teva intends to establish a collection of documents that the system says are unlikely to be responsive, and which they will not

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review, let alone produce. This was never contemplated when the parties devoted their time and effort and the Court made clear its intention to get this groundwork behind us last year. Since the purported compelling need for a 180 degree shift from search terms to TAR is based on a flawed rationale, and there is certainly no need to do this, the proposal should be precluded.

The Case Law Strongly Supports Plaintiffs' Position

Teva has also cited to a string of cases that hold directly against its position or have no applicability to the issue here. The first five cases cited by Teva in its letters to Plaintiffs strongly support a determination that Teva cannot utilize TAR here for production purposes. As argued during the conference, the *Progressive Cas. Ins.* case is directly on point and presents a well-reasoned analysis for why this belated effort to layer TAR on a search terms narrowed set of documents should be denied. That Court took the defendant complaining of cost at its word and ordered production of all the documents hit by the search terms, a result Plaintiffs request here if Teva is permitted to utilize CMML. Likewise, *In re Mercedes-Benz* makes clear that where a defendant chooses to use search terms, and the plaintiffs and the Court rely on and implement that selection, the defendant cannot be permitted to later upend the process and seek to change the methodology when it has buyer's remorse. Ultimately, the roadmap for a smooth, fair application of any type of TAR requires full cooperation and coordination between the parties, especially in a complex MDL – as occurred in the *In re Actos* MDL discussed in Plaintiffs' prior letter. In *Actos*, the parties' experts worked together from day one to establish the parameters

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and implement the application of TAR against the entire data set, rather than an artificially narrowed set as proposed here. See Also: Jonathan Jaffe Declaration.

During the July 15, 2020 conference defense counsel cited to yet another case *In re Broiler Chicken Antitrust Litig.*, No. 1:16-CV-08637, 2018 WL 1146371 (N.D. Ill. Jan. 3, 2018) claiming that it supported the position that its last second disclosure of unilateral use of TAR layered on a narrowed set of documents established through application of search terms is something that has been approved in other cases. In point of fact, that case is very different, and the contrast further demonstrates why Teva's sandbag introduction of a TAR proposal is unworkable here.

In *Broiler Chicken*, the timing and process by which the parties established the parameters of the Order Regarding Search Methodology for Electronically Stored Information was radically different from what Teva is attempting to do here. First, as is evident from the face of the Order, but also looking at the docket history, the parties negotiated that protocol at the very start of the discovery process, prior to any negotiation of custodians, search terms, etc., all of which occurred in this case last year. Second, that protocol was heavily negotiated and was arrived at with the assistance of an electronic discovery special master appointed by the Court. If Defendants had wanted to do something similar here, they should have approached Plaintiffs more than one year ago. Instead, Teva fully engaged in working to establish a search terms methodology, with the actual search terms negotiations beginning in or about September 2019. Third, the procedure provides a detailed roadmap of how both the TAR/CAL process is to be

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implemented, requiring the parties to work together, with disputes resolved there by the special master. None of that exists here.

Fourth, and most importantly, the procedure provided a detailed roadmap of best practices for how search terms are agreed to, including hit counts, sampling, and provision to the requesting party of contextual examples of false positives, all of which Plaintiffs requested Defendants to do in the September to December search term negotiation time frame and which Defendants adamantly refused to do. This was discussed during the July 15, 2020 hearing with Plaintiffs' citation to the November 30, 2019 hearing transcript which was one of numerous times that Plaintiffs noted Defendants' refusal to run tests, and work collaboratively with Plaintiffs to utilize the data in constructing the process. Plaintiffs did not have access to this information, such as the exemplar false positive documents, even during the last round of belated search term renegotiation and litigation.

It is also critical to note that when the parties here were negotiating the *initial* December search terms, unlike the case in *Broiler Chicken*, Plaintiffs had no expectation that there was going to be any possibility of further restriction of the corpus of documents to be reviewed. This holds doubly true for the narrowed search terms agreed to by the parties *just last month*. Both negotiations would have looked very different if Teva had timely disclosed its intentions, and the parties had a procedure like that in *Broiler Chicken* in place at the beginning of the process.

Therefore, Defendants' reliance on the *Broiler Chicken* case is misplaced, and as with the other cases discussed above, strongly supports Plaintiffs' position. Given that

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rolling productions have already begun, and that productions have been ordered to be *completed* by November, nothing in *Broiler Chicken* supports Defendants' unilateral attempt to inject TAR/CAL at this late stage.

Responses to the Court's Inquiries

The Court's communication requesting responses to several pointed questions is very helpful to crystallize the issues.

First, if Teva is permitted to utilize CMML, the only fair and workable solution to the reservoir of documents deemed "non-responsive" would be for the entire group of documents to be produced to Plaintiffs as soon as possible. These documents would require a full review since there is simply insufficient time at this stage of the litigation to negotiate, establish, and implement an even-handed protocol that would guarantee adequate quality control of so-called non-responsive documents on the review and production side. This issue is further addressed, along with the bulk of the technical issues relevant to this dispute, in the attached Declaration of Jonathan Jaffe, Plaintiffs' e-discovery consultant in this litigation.

Second, the Court directed Teva to advise as to whether it agrees to disclose the definition of "responsive" that it is utilizing. Continued failure by Teva to agree to this basic request would be completely unreasonable. As the Court is aware, Teva refused to disclose this fundamental input to the process, instead talking about generalities and the need for Plaintiffs to trust the defense reviewers to understand the litigation. Ultimately, Plaintiffs are unlikely to agree to the unilaterally selected definition, and the only feasible

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way to make this a truly fair and productive process would be for Plaintiffs to have full input into establishing the definition to be applied.

Third, in response to the Court's inquiry as to what other tags Plaintiffs would request if this process were to go forward, Mr. Jaffe has addressed that question in detail in his Declaration. It must be noted that the proposed tags are not exhaustive, and would almost certainly require significant refinement if the necessary free flow of information about the system were to occur.

Fourth, in response to the Court's inquiry as to whether the original search term list could be utilized if TAR is applied, this would be technically feasible, as the prior search terms construct could be run, and from Plaintiffs' perspective that would be better than application to the document set produced from the narrowed search terms. However, this would not solve the foundational problem with applying TAR to a search term narrowed set of documents for production purposes – TAR is intended to be run on the entire document set, from the outset, based on a thoughtfully applied set of tags, with continual quality control by both the producing and receiving party. The time to talk about doing that was one year ago.

Finally, the Court addressed the requirement that the Plaintiffs' prioritization requests be adhered to. As set forth in Mr. Jaffe's Declaration, that is not how CMML functions. The fact that some documents falling into the prioritization categories may be produced is not a substitute for the type of focused searching and production efforts that were contemplated by the prioritization order. It is simply impossible for Plaintiffs to confidently evaluate the production since Plaintiffs have no idea as to the full scope of

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what is there, however even at this early stage it appears that certain important, prioritized categories have not been produced, including for example in-process testing of the valsartan API and finished dose, OOS and OOT investigations of the finished dose products, and deviation inspection reports. Most important, as set forth above, even to the extent documents were produced touching on the prioritization categories this does not prove completeness.

Other Defendants Should Also Be Precluded

Finally, it is critical to address what occurred as the argument progressed on July 15, 2020. As they saw what Teva was striving for, and perceived that Teva could potentially prevail on this issue, ZHP and Mylan tried to benefit as well, opportunistically claiming for the first time that they too intended to follow this blueprint.

It is difficult to understand how those defendants could think it permissible or credible to never raise TAR, staying silent even as the issue was crystallized when the agenda letters were filed, and then jump in during the argument to blithely tell the Court and Plaintiffs that they too harbored an even more secret intent to layer in TAR at the end to cut off documents from being reviewed. Obviously, this was an afterthought in real time. This should not be rewarded, and the mischief introduced by Teva's TAR request should not be permitted to seed similar efforts by co-defendants.

Conclusion

For the foregoing reasons, Plaintiffs request entry of an Order precluding the use of the proposed CMML system (or any other TAR 1.0 or continuous active learning system) by Teva, or any other defendant, in connection with the review of ESI for

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production. In the event the use of a continuous active learning system is permitted to any extent, it should be limited to the review of custodial e-mails only, should be limited to textual documents (e.g., all graphs, charts, data files, excel files, audio files, video files, etc. should be excluded from the process even if they are attachments to custodial e-mails), and defendants should be limited to using such process solely for purposes of prioritizing review and be prohibited from excluding any documents from review, with all of the “non-responsive” documents to be produced to Plaintiffs.

Respectfully,



Adam M. Slater